

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
21 February 2002 (21.02.2002)

PCT

(10) International Publication Number
WO 02/14537 A3

(51) International Patent Classification⁷: **A61K 31/195**,
G01N 33/00, A61K 38/22

(21) International Application Number: PCT/US01/25343

(22) International Filing Date: 14 August 2001 (14.08.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/224,991 14 August 2000 (14.08.2000) US

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(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:
10 May 2002

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHODS FOR DIAGNOSING AND TREATING DYSAUTONOMIA AND OTHER DYSAUTONOMIC CONDITIONS

(57) Abstract: Methods for aiding in the diagnosis of dysautonomic disorders and dysautonomic conditions and methods for treating individuals diagnosed as having a dysautonomic disorder or a dysautonomic condition. In one aspect, a diagnosis method comprising analyzing a stool sample of an individual for the presence of a biological marker wherein the quantity of the biological marker is an indication of whether the individual has, or can develop, a dysautonomic disorder or dysautonomic condition, as well as a therapeutic method for treating a dysautonomic disorder or dysautonomic condition by administration of, e.g., secretin, neuropeptides, peptides and/or digestive enzymes.

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 01/25343

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/195 G01N33/00 A61K38/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, CHEM ABS Data, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	AXELROD, FELICIA: "Grant Reciept awards March - May 2000. Secretin treatment for gastrointestinal dysmobility in patients with familial dysautonomia" INTERNET: NEY YORK UNIVERSITY OF MEDICINE, 'Online! XP002191208 Retrieved from the Internet: <URL:mcr4.med.nyu.edu/ogars/awards/award_s_2000/page2.html> 'retrieved on 2002-02-25! the whole document ---	1
A	US 5 958 875 A (MANTHORPE MARSTON ET AL) 28 September 1999 (1999-09-28) column 10, line 11 - line 23; claims 1-14 --- -/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search

25 February 2002

Date of mailing of the international search report

11/03/2002

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/25343

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 22499 A (BRAUN PETER ERICH ;MCKERRACHER LISA JOAN (CA); DAVID SAMUEL (CA);) 28 May 1998 (1998-05-28) claims 1-47 -----	
A	US 5 648 335 A (LEWIS MICHAEL E ET AL) 15 July 1997 (1997-07-15) column 8, line 38 - line 51; claims 1-3 -----	
A	WO 95 22344 A (BRAUN PETER ERICH ;MCKERRACHER LISA JOAN (CA); UNIV MCGILL (CA); D) 24 August 1995 (1995-08-24) claims 1-13 -----	
A	EP 0 564 739 A (YSSUM RESEARCH DEVELOPMENT CO OF THE HEBREW UNIVERSITY OF JERUSALEM) 13 October 1993 (1993-10-13) page 14, line 56 -page 15, line 6 -----	
A	US 6 020 314 A (MCMICHAEL JOHN) 1 February 2000 (2000-02-01) abstract -----	
A	WO 99 64059 A (REPLIGEN CORP) 16 December 1999 (1999-12-16) abstract -----	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 1-57 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the secretin compound/composition.

Continuation of Box I.1

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/25343

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5958875	A	28-09-1999	AU 2426497 A WO 9736607 A1	22-10-1997 09-10-1997
WO 9822499	A	28-05-1998	CA 2190418 A1 AU 5044298 A WO 9822499 A2	15-05-1998 10-06-1998 28-05-1998
US 5648335	A	15-07-1997	US 5569648 A US 5420112 A AT 187889 T AU 683215 B2 AU 4526293 A CA 2136969 A1 DE 69327402 D1 DE 69327402 T2 DK 659083 T3 EP 0659083 A1 ES 2140463 T3 GR 3032844 T3 HU 70450 A2 JP 7507799 T NO 944780 A NZ 253867 A NZ 280523 A PT 659083 T WO 9325219 A1 US 5633228 A RU 2120803 C1	29-10-1996 30-05-1995 15-01-2000 06-11-1997 04-01-1994 23-12-1993 27-01-2000 04-05-2000 13-06-2000 28-06-1995 01-03-2000 31-07-2000 30-10-1995 31-08-1995 09-12-1994 27-08-1996 27-07-1997 31-05-2000 23-12-1993 27-05-1997 27-10-1998
WO 9522344	A	24-08-1995	AU 1703595 A CA 2183630 A1 WO 9522344 A1	04-09-1995 24-08-1995 24-08-1995
EP 0564739	A	13-10-1993	AT 189228 T DE 69230610 D1 DE 69230610 T2 EP 0564739 A2 JP 6263797 A US 5723575 A US 6117974 A	15-02-2000 02-03-2000 28-12-2000 13-10-1993 20-09-1994 03-03-1998 12-09-2000
US 6020314	A	01-02-2000	AU 4985499 A EP 1105147 A1 WO 0009142 A1	06-03-2000 13-06-2001 24-02-2000
WO 9964059	A	16-12-1999	US 6197746 B1 AU 4432299 A EP 1085901 A2 WO 9964059 A2 US 2001049353 A1	06-03-2001 30-12-1999 28-03-2001 16-12-1999 06-12-2001